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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,001	09/30/2004	Masayuki Amagai	4439-4025	3825
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MORGAN & FINNEGAN, L.L.P. 3 WORLD FINANCIAL CENTER NEW YORK, NY 10281-2101			EXAMINER GAMBEL, PHILLIP	
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			06/12/2008	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/510,001	<b>Applicant(s)</b> AMAGAI ET AL.	
	<b>Examiner</b> Phillip Gambel	<b>Art Unit</b> 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12/19/07; 1/11/08.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

1. In view of applicant's communication entitled Responsive to the Notice of Non-Compliant Amendment dated December 19, 2007, filed 01/22/2008, and discussions on 01/17/2008 and 01/22/2008;

applicant's request for reconsideration of prosecuting the method claims, filed 12/19/2007, are under consideration in the interest of compact prosecution.

However, in contrast to applicant's reliance upon Unity of Invention under 37 CFR 1.475, the following is noted.

It is noted that the original claims did not provide a contribution over the prior art as taught by Black et al. (U.S. Patent No. 6,001,358) (892; of record) as set forth in the Office Actions, mailed 03/29/2007 and 09/14/2007.

Further, as indicated herein / below, Black et al. (U.S. Patent No. 6,001,358) (892; of record) does not provide a contribution over the prior art as it reads on the current method claims as well.

The agreement reached during the telephonic interview conducted between the applicant and the examiner was that the examiner would examine the method claims in the RCE, even though the previous claims were drawn only to product claims in the interest of compact prosecution.

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission, filed on 11/26/2007, has been entered.

Applicant's amendment, filed 12/19/2007, has been entered.

Claims 1 and 3 have been amended.

Claims 1 and 3 are pending and being acted upon in the instant application.

Claims 2 and 4 have been canceled previously.

Again, it is noted that for examination purposes, the claimed recitations of "a remedy" and a preventive agent" are read as compositions or formulations comprising a CD40L antagonist (e.g., see page 9, paragraph 2 of the instant specification).

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2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Upon consideration of applicant's amendment, filed 06/29/2007; the previous rejection under 35 U.S.C. § 112, second paragraph, has been withdrawn.

4. Claims 3 is rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention essentially for the reasons of record.

Applicant's arguments, filed 06/29/2007, have been fully considered but have not been found convincing essentially for the reasons of record.

Applicant asserts that pemphigus is induced by autoantibodies against desmoglein and that the mouse model, as exemplified in the instant specification, would be the appropriate model for human therapy.

Although not cited on an Information Disclosure Statement, applicant further relies upon the submission of the Abstracts only of Starzycki, et al. (International Journal of Dermatology 37(3):211-214, 1998), Katzenelson, et al. Dermatologica 181 (1):48-50, 1990) and Tur, et al. (Arch Dermatol. 134(11 ): 1406-1410, 1998) to support the position that it was known that certain people were predisposed to pemphigus and that there were instances where it would be useful to utilize the instant invention to prevent the onset of pemphigus.

Applicant further asserts that the instant invention could be utilize to prevent the reoccurrence of the disease.

The problem here is that applicant has not provided direction in the application as-filed to teach the skilled artisan how to make and use the information that certain people were predisposed to pemphigus or to utilize anti-CD40L antibodies the to prevent the reoccurrence of the disease.

Further, applicant has not sufficiently addressed the unpredictability and inconsistency of treating patients with pemphigus, as evidenced by The Merck Manual of Diagnosis and Therapy, Seventeenth Edition (edited by Beers et al., Merck Research Laboratories, Whitehouse Station, NJ, 1999; see pages 829-831) (892; of record) and reiterated below.

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Also, with respect to animal models, applicant has not sufficiently addressed the following also of record and reiterated below.

Also, it is noted that experimental protocols usually are conducted under defined conditions wherein the antagonist and the stimulus / insult occur at the same or nearly the same time. Immunosuppression is much easier to achieve under such controlled conditions that experienced in the human disorders or diseases such as pemphigus targeted by the claimed "preventative agents". With respect to in vivo studies, animal models validate concepts based on studies of human disease, such studies are limited to the "acute" as opposed to "chronic" nature of the disease. In animal models, the onset of inflammation is rapid with an aggressive destructive process, whereas in humans the disease progresses more slowly, often with natural periods of disease exacerbation and remission. Generally, such diseases are diagnosed only after significant tissue damage has occurred.

The following is reiterated for applicant's convenience.

In vitro and animal model studies have not correlated well with in vivo clinical trial results in patients. Since the therapeutic indices of immunosuppressive drugs or biopharmaceutical drugs can be species- and model-dependent, it is not clear that reliance on the in vitro and in vivo experimental observations as well as the clinical experience with targeting various inflammatory conditions with CD40L- specific antibodies accurately reflects the relative ability or efficacy of the claimed "preventative agents" to prevent pemphigus.

Pharmaceutical therapies in the absence of in vivo clinical data are unpredictable for the following reasons; (1) the protein may be inactivated before producing an effect, i.e. such as proteolytic degradation, immunological inactivation or due to an inherently short half-life of the protein; (2) the protein may not reach the target area because, i.e. the protein may not be able to cross the mucosa or the protein may be adsorbed by fluids, cells and tissues where the protein has no effect; and (3) other functional properties, known or unknown, may make the protein unsuitable for in vivo therapeutic use, i.e. such as adverse side effects prohibitive to the use of such treatment. See page 1338, footnote 7 of Ex parte Aggarwal, 23 USPQ2d 1334 (PTO Bd. Pat App. & Inter. 1992).

The specification does not adequately teach how to effectively prevent pemphigus by administering CD40L-specific antibodies / CD40L antagonists. The specification does not teach how to extrapolate data obtained from various in vitro or in vivo observations as well as clinical experience with CD40L-specific antibodies / CD40L antagonists to the development of effective methods of preventing pemphigus in humans broadly encompassed by the claimed invention.

Also, it is noted that experimental protocols usually are conducted under defined conditions wherein the antagonist and the stimulus / insult occur at the same or nearly the same time. Immunosuppression is much easier to achieve under such controlled conditions that experienced in the human disorders or diseases such as pemphigus targeted by the claimed "preventative agents". With respect to in vivo studies, animal models validate concepts based on studies of human disease, such studies are limited to the "acute" as opposed to "chronic" nature of the disease. In animal models, the onset of inflammation is rapid with an aggressive destructive process, whereas in humans the disease progresses more slowly, often with natural periods of disease exacerbation and remission. Generally, such diseases are diagnosed only after significant tissue damage has occurred.

For example, The Merck Manual of Diagnosis and Therapy, Seventeenth Edition (edited by Beers et al., Merck Research Laboratories, Whitehouse Station, NJ, 1999; see pages 829-831) indicates that:

Pemphigus is a serious disease with an inconsistent and unpredictable response to therapy and that the aim of treatment is to stop the eruption of new lesions.

See Treatment on page 829.

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Therefore, the treatment of pemphigus is drawn to the treatment of the disease and its associated lesions subsequent to an individual being diagnosed with pemphigus and not as a preventative agent of the disease itself, as recited in the current claims.

There is insufficient guidance and direction as well as objective evidence to provide for preventing pemphigus recited in the instant claims.

In view of the lack of predictability of the art to which the invention pertains the lack of established clinical protocols for effective methods to prevent pemphigus with therapeutic agents, undue experimentation would be required to practice the claimed "preventative agents" to prevent pemphigus with a reasonable expectation of success, absent a specific and detailed description in applicant's specification of how to effectively practice the claimed "preventative agents" and absent working examples providing evidence which is reasonably predictive that the claimed "preventative agents" are effective for preventing pemphigus encompassed by the claimed products.

Applicant's arguments have not been found persuasive.

Again, applicant is invited to amend the claims to avoid the recitation of "a preventive agent".

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1 and 3 are rejected under 35 U.S.C. § 102(b) as being anticipated by Black et al. (U.S. Patent No. 6,001,358) (see entire document) alone essentially for the reasons of record or in further evidence by The Merck Manual of Diagnosis and Therapy, Seventeenth Edition (edited by Beers et al., Merck Research Laboratories, Whitehouse Station, NJ, 1999; see pages 829-831) (892; or record).

Applicant's arguments, filed 06/29/2007, have been fully considered but have not been found convincing essentially for the reasons of record.

In contrast to applicant's assertions that the prior art does not disclose that the anti-CD40L antibody is effective in preventing pemphigus, does not provide experimental data and is an incomplete invention,

applicant is reminded that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See In re Casey, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963). Also, see MPEP 2111.02

Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

Further, applicant ignores the claims of Black et al. (U.S. Patent No. 6,001,358).

U.S. patents are presumed valid by U.S. courts unless proven otherwise. See 35 U.S.C. 282.

Also, it is noted that proof of efficacy is not required in order for prior art reference to be enabling for purposes of anticipation. See Impax Laboratories Inc. v. Aventis Pharmaceuticals Inc., 81 USPQ2d 1001 (Fed. Cir. 2006).

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Given the broadest reasonable interpretation of the claims, including preventing the development of pemphigus as reading on treating a patient with pemphigus or characteristics of pemphigus and preventing its further development, which is consistent with the instant specification (e.g., see page 3, paragraph 1 and the Disclosure of the Invention on pages 3-5 of the instant specification).

Also, given the broadest reasonable interpretation of the claims and the nature of treating pemphigus, which involves a long course of therapy which aims includes immediate and subsequent to stop the eruption of new lesions, as evidenced by the Merck Manual,

the prior art teaching of treating pemphigus with anti-CD40L antibodies reads on treating and in turn, preventing pemphigus as it reads on preventing the eruption of new lesions in the long course of treatment of this disease (e.g., see pages 829-831, particularly Treatment).

The following is reiterated for applicant's convenience.

Black et al. teach antagonistic anti-CD40L antibodies, including compositions thereof (e.g., see columns 34-38) as well as their use in the inhibition of CD40L:CD40- mediated interactions, including the treatment of autoimmune and non-autoimmune conditions (e.g., see columns 31-34), including pemphigus (e.g., see column 33, lines 4-5) (see entire document, including Summary of the Invention, Detailed Description of the Invention and Claims). Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced antagonistic anti-CD40L antibodies and therapeutic compositions thereof.

Applicant's arguments have not been found persuasive.

7. Claims 1 and 3 are rejected under 35 U.S.C. § 102(e) as being anticipated by Black et al. (U.S. Patent No. 7,122,187) (see entire document) alone

or in further evidence by The Merck Manual of Diagnosis and Therapy, Seventeenth Edition (edited by Beers et al., Merck Research Laboratories, Whitehouse Station, NJ, 1999; see pages 829-831) (892; of record).

Black et al. teach antagonistic anti-CD40L antibodies, including compositions thereof (e.g., see columns 34-38) as well as their use in the inhibition of CD40L:CD40- mediated interactions, including the treatment of autoimmune and non-autoimmune conditions (e.g., see columns 31-34), including pemphigus (e.g., see column 33, lines 4-5) (see entire document, including Summary of the Invention, Detailed Description of the Invention and Claims).

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced antagonistic anti-CD40L antibodies and therapeutic compositions thereof.

In addition to the teachings of Black et al. (U.S. Patent No. 6,001,358) of record and set forth above,



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Black et al. (U.S. Patent No. 7,122,187) has been added in that this patent includes claimed methods of treating pemphigus (e.g., see Claim 1).

U.S. patents are presumed valid by U.S. courts unless proven otherwise. See 35 U.S.C. 282.

Given the broadest reasonable interpretation of the claims, including preventing the development of pemphigus as reading on treating a patient with pemphigus or characteristics of pemphigus and preventing its further development, which is consistent with the instant specification (e.g., see page 3, paragraph 1 and the Disclosure of the Invention on pages 3-5 of the instant specification).

Also, given the broadest reasonable interpretation of the claims and the nature of treating pemphigus, which involves a long course of therapy which aims includes immediate and subsequent to stop the eruption of new lesions, as evidenced by the Merck Manual, the prior art teaching of treating pemphigus with anti-CD40L antibodies reads on treating and in turn, preventing pemphigus as it reads on preventing the eruption of new lesions in the long course of treatment of this disease (e.g., see pages 829-830, particularly Treatment).

8. Claims 1 and 3 are rejected under 35 U.S.C. § 102(e) as being anticipated by Di Padova et al. (US 2004/0038293 A1) (see entire document) alone

or in further evidence by The Merck Manual of Diagnosis and Therapy, Seventeenth Edition (edited by Beers et al., Merck Research Laboratories, Whitehouse Station, NJ, 1999; see pages 829-831) (892; of record).

Di Padova teach antagonistic anti-CD40L antibodies, including compositions thereof (e.g., see paragraphs [0086] and [0090] – [0091] ) as well as their use in the inhibition of CD40L:CD40- mediated interactions (see entire document), including the treatment of autoimmune and non-autoimmune conditions (e.g., see paragraphs [0081] – [0101], including pemphigus (e.g., see paragraph [0083] and Claim 10) (see entire document, including Claims).

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced antagonistic anti-CD40L antibodies and therapeutic compositions thereof in their treatment of pemphigus.

Given the broadest reasonable interpretation of the claims, including preventing the development of pemphigus as reading on treating a patient with pemphigus or characteristics of pemphigus and preventing its further development, which is consistent with the instant specification (e.g., see page 3, paragraph 1 and the Disclosure of the Invention on pages 3-5 of the instant specification).

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Given the broadest reasonable interpretation of the claims, including preventing the development of pemphigus as reading on treating a patient with pemphigus or characteristics of pemphigus and preventing its further development, which is consistent with the instant specification (e.g., see page 3, paragraph 1 and the Disclosure of the Invention on pages 3-5 of the instant specification).

Also, given the broadest reasonable interpretation of the claims and the nature of treating pemphigus, which involves a long course of therapy which aims includes immediate and subsequent to stop the eruption of new lesions, as evidenced by the Merck Manual, the prior art teaching of treating pemphigus with anti-CD40L antibodies reads on treating and in turn, preventing pemphigus as it reads on preventing the eruption of new lesions in the long course of treatment of this disease (e.g., see pages 829-831, particularly Treatment).

It is noted that Di Padova et al. also teaches “treatment and/or prevention diseases or disorders” (e.g., see paragraph [0083] ).

9. Claim 3 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Black et al. (U.S. Patent No. 7,122,187) OR Di Padova et al. (US 2004/0038293 A1) in view of The Merck Manual of Diagnosis and Therapy, Seventeenth Edition (edited by Beers et al., Merck Research Laboratories, Whitehouse Station, NJ, 1999; see pages 829-831) (892; of record).

Given applicant’s arguments concerning the recitation of “preventing pemphigus”, This obviousness rejection has been set forth as it reads on the broadest reasonable interpretation of the claims and to address applicant’s arguments.

Black et al. teach antagonistic anti-CD40L antibodies, including compositions thereof (e.g., see columns 34-38) as well as their use in the inhibition of CD40L:CD40- mediated interactions, including the treatment of autoimmune and non-autoimmune conditions (e.g., see columns 31-34), including pemphigus (e.g., see column 33, lines 4-5) (see entire document, including Summary of the Invention, Detailed Description of the Invention and Claims).

Di Padova teach antagonistic anti-CD40L antibodies, including compositions thereof (e.g., see paragraphs [0086] and [0090] – [0091] ) as well as their use in the inhibition of CD40L:CD40- mediated interactions (see entire document), including the treatment of autoimmune and non-autoimmune conditions (e.g., see paragraphs [0081] – [0101], including pemphigus (e.g., see paragraph [0083] and Claim 10) (see entire document, including Claims).

Given the broadest reasonable interpretation of the claims, including preventing the development of pemphigus as reading on treating a patient with pemphigus or characteristics of pemphigus and preventing its further development, which is consistent with the instant specification (e.g., see page 3, paragraph 1 and the Disclosure of the Invention on pages 3-5 of the instant specification).

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Also, given the broadest reasonable interpretation of the claims and the nature of treating pemphigus, which involves a long course of therapy which aims includes immediate and subsequent to stop the eruption of new lesions, as evidenced by the Merck Manual,

the prior art teaching of treating pemphigus with anti-CD40L antibodies reads on treating and in turn, preventing pemphigus as it reads on preventing the eruption of new lesions in the long course of treatment of this disease (e.g., see pages 829-831, particularly Treatment).

Further, it is noted that the Merck Manual teaches Diagnosis of Pemphigus in order to determine the population of interest for treatment (e.g., see page 829).

It is noted that Di Padova et al. also teaches "treatment and/or prevention diseases or disorders" (e.g., see paragraph [0083] ).

One of ordinary skill in the art at the time the invention was made would have been motivated to select treating patients diagnosed with pemphigus or as an ongoing treatment in order to stop the eruption of new lesions in order to prevent the pemphigus or the characteristics of pemphigus with anti-CD40L antibodies, given the teachings of the primary references as to the applicability of anti-CD40L antibodies in the treatment of pemphigus. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

"The test of obviousness is not express suggestion of the claimed invention in any or all of the references but rather what the references taken collectively would suggest to those of ordinary skill in the art presumed to be familiar with them." See In re Rosselet, 146 USPQ 183, 186 (CCPA 1965).

"There is no requirement (under 35 USC 103(a)) that the prior art contain an express suggestion to combine known elements to achieve the claimed invention. Rather, the suggestion to combine may come from the prior art, as filtered through the knowledge of one skilled in the art." Motorola, Inc. v. Interdigital Tech. Corp., 43 USPQ2d 1481, 1489 (Fed. Cir. 1997).

An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of a case. Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not. See KSR Int'l Co. v. Teleflex Inc., 550 U.S., 2007 U.S. LEXIS 4745, 2007 WL 1237837, at \*12 (2007) ("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.").

10. No claim is allowed.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571) 272-0878.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phillip Gambel/

Phillip Gambel, Ph.D., J.D.  
Primary Examiner  
Technology Center 1600  
Art Unit 1644  
June 9, 2008